



Corporate Regulatory Affairs

Abbott Laboratories

D-387 Building AP6C
100 Abbott Park Road
Abbott Park, IL 60064-6091

September 7, 1999

The Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane Room 1061
Rockville, MD 20857

RE: Comments on the FDA's Draft Guidance for FDA Staff on Civil Money Penalty
[Docket No. 99D-1273]

Dear Sirs or Madams:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

I. GENERAL REMARKS

- A. Abbott generally supports the August 13, 1999 response to this same **subject** sent to the FDA by the Health Industry Manufacturers Association (HIMA).
- B. Since the Agency is receiving numerous **comments** on this **proposal**, we suggest a series of public **meetings where various** opinions, both **supporting** and dissenting, can be discussed **prior to finalizing the guidance document**.
- C. For this draft, the Agency appears to have **by-passed its own policies and practices** by distributing a **draft guidance directly** to the field. This can be referenced in the Federal Register from February 27, 1997, "The Food and Drug Administration's Development, Issuance and Use of Guidance Documents", Docket No. 95P-0110.

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- D. The Agency should formally clarify the relationship between this draft guidance **and the recently issued draft guidance on: (a) Scientific Dispute Resolution, Docket No. 99D-0239 and the finalized guidance: (b) Medical Device Appeals and Complaints - Guidance on Dispute Resolution, issued in February of 1998.**
- E. The Agency should review the wording at the end of the fourth paragraph, page one, of the Guidance titled, **Safe Medical Devices Act Civil Money Penalty Decision Tree**: "Companies that wish to avoid hearings 'may resolve the dispute by entering into consent agreements.'" In contrast to this draft, the final guidance on Medical Device Appeals and Complaints lists as many as nine different means to resolving disputes.

II. SPECIFIC COMMENTS

1. In the section entitled "Background," correct the citation to the Federal Food, Drug and Cosmetic Act (Act) for Civil Money Penalty (CMP) actions from **303(f) to 303(g).**
2. In applying CMP to GMP violations, the terms "significant departure" and "knowing departure" are used in the Act. Each of these terms is defined under 21 CFR 17.3. However, in this draft guidance document, FDA fails to adhere to these terms of the Act when it directs Districts to consider CMP action for Situation 1 GMP deficiencies. Districts are instructed to look for "closely related GMP deficiency observations," yet the regulations require a much more stringent assessment, i.e., "a departure from requirements that is either a single major incident or a series of incidents that collectively are consequential. This guidance document fails to give consideration to the terms, "significant departure" and "knowing departure" as defined in the regulations. We urge the Agency to **re-evaluate** its application of CMP to GMP violations taking **into** consideration the terms "significant departure" and "knowing departure" **as defined** in the regulations.
3. The guidance document relies on Situation 1 GMP deficiencies **defined** under **C.P. 7382.830, dated May 4, 1995. This document predates the Quality System Regulations and FDAMA.** More importantly, the **Compliance Program Manual for the Inspection of Medical Devices** is currently under revision. The **"Draft Compliance Program Guidance Manual: Inspection of Medical Devices"** is a **draft guidance document** currently available for public comment. Rather than relying on a soon-to-be-replaced policy to establish the applicability of **CMP to significant or knowing departures of GMP** regulations, we urge the Agency to adopt the final edition of the "Compliance

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Program Manual for the Inspection of Medical Devices" as a source for defining when GMP violations may be subject to CMP.

4. **Before implementing a CMP program designed to "influence" compliance, the Agency should focus on improvements to the current system which would enhance voluntary compliance. Currently, it is extremely difficult for a firm to obtain copies of Establishment Inspection Reports (EIRs) or information regarding classification of an inspection as OAI. Under the current system, it is extremely difficult for a firm to get a complete understanding of Agency concerns. Therefore, despite guidance direction to provide firms with warnings prior to CMP actions, CMP regulatory action will be taken against a firm without the firm having a complete understanding of its compliance standing. Furthermore, the inability of firms to obtain EIRs or inspection status prohibits firms from achieving voluntary compliance, which is one avenue in providing greater benefit to the public health than forced compliance through Agency remedial action.**
5. The **general philosophy of CMP, as described in the guidance document, is of concern. The guidance document states " [CMP] is designed to influence future conduct of the affected firm and/or other firms. .. With this philosophy, it is difficult to understand how the Agency will exercise the use of CMP in a fair and reasonable manner. An Agency looking to influence other firms will take remedial action against those firms with a recognizable name, size and presence creating significant issues for such firms. Additional safeguards are needed to prevent the use of CMP in this manner.**
6. In publishing the final CMP rule, the Agency stated, "FDA agrees that it is important to exercise enforcement discretion in a fair and **reasonable** manner. Due to the newness of **the** civil penalty authority and the lack of FDA precedents in this area, the Office of Regulatory Affairs will establish coordinating procedures to help assure consistent policies in exercising civil money penalties authority agency wide." (60 FR 38614). Despite **these assurances** from the Agency, the **draft** guidance document gives considerable discretion to the District **Offices**. By giving such discretion to the District Offices, the Agency has created **a** system susceptible to varying applications. Additional **assurances** are **needed to ensure CMP actions are** executed in a fair and reasonable manner.
7. The document fails to take **into consideration mitigating** factors when assessing CMP actions. It is recommended that the Agency take into consideration factors such as a firm's **voluntary** action to work with the **Agency** (especially in areas where FDA policy is unclear), or devices which represent a public health concern (e.g., the only available device or devices representing improvements over similarly marketed devices).

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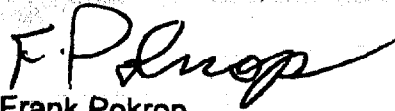
8. In the section of the document entitled "Civil Money Penalty Decision Tree," FDA provides examples of prior warning. FDA lists "warning letter, civil suit, administrative action, or other regulatory correspondence" as examples of prior warning. We recommend striking "other regulatory correspondence." Because of the broad nature of the phrase it is difficult to understand exactly what it means. More importantly, this all-encompassing term could refer to any FDA document, independent of whether or not the firm or individual has received the correspondence. In such circumstances, the firm or individual would not have received prior warning, defeating the intent of this section. FDA provides "discussion of objectionable conditions with a responsible individual of the firm and an FDA investigator that have been documented in the establishment inspection report" as an example of prior warning. Establishment inspection reports are not readily available to firms, especially firms with alleged regulatory violations. Until such reports are readily available to firms, this example should be stricken from the guidance document. An Establishment Inspection Report, containing allegations of regulatory violations, which is not available to a firm, fails to serve as prior warning. FDA provides "verbal notification from Agency officials to a firm's top management, e.g., in meetings or telephone conversations confirmed in writing" as an example of prior warning. It is requested that FDA clarify this statement to make it clear that both meetings and telephone conversations must be confirmed in writing and mailed to the firm.

FDA provides "industry meetings during which pertinent violations are discussed if attendance by a firm's representative is documented" as an example of prior warning. We recommend striking this provision as it creates a number of issues. For a large corporation a number of individuals may attend an industry meeting. For example, individuals responsible for pharmaceutical products may attend a meeting which involves medical device discussions. However, such an individual may not comprehend the significance of the information pertaining to medical devices. Individuals from areas which do not have regulatory responsibility (e.g., research and development) may attend a medical device industry meeting. Again, such individuals may not comprehend the significance of the information presented. Additionally, an individual may step out of the room at the time the significant information had been communicated. Attendance records -- would-demonstrate the individual-was at the meeting. However, the firm would fail to receive prior warning.-

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Abbott Laboratories appreciates the opportunity to comment on FDA drafts.

Yours truly,



Frank Pokrop
Director, Corporate Regulatory Affairs
(847) 937-8473
FAX: (847) 938-3106

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cc: Andrea P. Latish (HFZ-330)
[Docket No. 99D-0239]
[Docket No. 95P-0110]